

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

NOVO NORDISK A/S, et al.,

Plaintiffs,

-vs-

Case No. 05-40188
Hon: AVERN COHN

CARACO PHARMACEUTICAL
LABORATORIES, LTD., et al.,

Defendants.

MEMORANDUM AND ORDER

I.

On September 13, 2010, the Court held an on-the-record conference with the parties relating to:

1. Caraco's Motion for a Protective Order re: Unrelated FDA Correspondence (Doc. No. 481); and
2. Novo's Motion to Dismiss for Lack of Subject Matter Jurisdiction (Doc. No. 478).

This memorandum and order memorializes the matters discussed at the conference and charts the future course of the case.

II.

The Court expressed a concern that it was not fully informed as to the background of the motion for protective order. After reviewing the file, it appears that the issue arose when Novo demanded that Caraco produce all of its correspondence with the FDA relating to its ANDA (because such correspondence was relevant to

jurisdiction) which culminated in an Order Granting Plaintiff's Motion to Compel Production of Documents (Doc. No. 62).

As noted during the conference, there is a certain disorder in the manner in which Novo is asking for documents at this time, and the manner in which Caraco has responded. The appropriate course is as follows:

1. The Order Granting Motion to Compel (Doc. No. 62) is VACATED.
2. Novo, to the extent it wants document production, shall file a demand for production in accordance with Fed. R. Civ. P. 34. If Caraco objects, it shall so state with its reasons. Novo may then move for an order compelling disclosure under Fed. R. Civ. P. 37. Alternately, Caraco may move for a protective order under Fed. R. Civ. P. 26(c).

This procedure will enable the Court to orderly dispose of Novo's request and Caraco's refusal.

III.

As noted above, Novo has moved to dismiss the case for lack of subject matter jurisdiction (Doc. No. 478); Caraco has responded (Doc. No. 493); Novo has replied (Doc. No. 495). As explicated in the record of the conference, this is a fact intensive motion.

Also important to the motion is some history. This is Novo's second motion. On July 9, 2008, Novo moved to dismiss for lack of jurisdiction (Doc No. 92). Caraco responded (Doc. No. 102). Thereafter, before the motion was resolved, the case was then assigned to the undersigned who had a status conference with the parties on July 29, 2008. On August 7, 2008, Novo withdrew the motion (Doc. No. 107). Novo's reasons for withdrawing the motion are not reflected in the record, except as to the

statement in the Notice of Withdrawal: "In light of actions taken and guidance provided by the Court during an in-chambers conference on July 29, 2008." The in-chambers conference was not on the record.

Novo's explanation of why it withdrew the motion as reflected in the transcript of the September 13, 2010, conference is not consistent with the Court's notes of the July 29, 2008 conference or the follow-up orders to that conference. The notes and orders reflect the following:

1. Initial status conference with the parties - July 29, 2008
 - discuss pending motion
 - plaintiff has filed a motion to dismiss (Doc. No. 92)
 - defendant has filed a response (Doc. No. 102)
 - reply due by Noon 08/08/2008
 - hearing to be set
2. Order - July 29, 2008 (Doc. No. 103)
 - "plaintiff's motion to dismiss for lack of jurisdiction is pending; oral argument on the motion will be held on Wednesday, September 03, 2008 at 2 pm"
3. Notice of Withdrawal of Plaintiff's Motion to Dismiss for Lack of Jurisdiction - August 07, 2008 (Doc. No. 107)

No useful purpose is served by attempting to resolve these differences. Suffice to say, Novo did not renew its effort to obtain dismissal on the grounds of lack of subject matter jurisdiction until the filing of its second motion on August 4, 2010, after completion of the trial on validity.

Also, during the trial on June 8, 2010, there was an extended colloquy with the Court when Caraco attempted to introduce in evidence, just prior to resting, several documents filed with the FDA on the grounds they were relevant to establishing the Court's subject matter jurisdiction. Novo, ironically, opposed these documents being part of the record (Tr. 06/08/2010, pp. 85-90). Novo also said in the course of the colloquy "There is no challenge to jurisdiction." (Tr. 06/08/2010, p. 88).

In any event, to adequately deal with the motion to dismiss, a firm understanding of the record of Caraco's efforts to obtain FDA approval of its ANDA is necessary.

Accordingly, Caraco shall have fifteen (15) days in which to file with the Court a statement of the material facts relating to its ANDA, in separately numbered paragraphs, from the date filed to today, which establish jurisdiction in the Court to adjudicate the validity of the '358 patent. Novo shall have ten (10) days thereafter to respond. No additional filings shall be allowed. Caraco's filing shall be accompanied by a book of exhibits of the relevant documents.

IV.

Also pending are:

1. Caraco's Proposed Findings of Fact (Doc. No. 498) and Trial Brief (Doc. No. 499);
2. Caraco's Notice of Renewed Motion and Renewed Motion For Summary Judgment On Sixth Affirmative Defense For Patent Misuse (Doc. No. 500) and accompanying documents (Docs. 501 and 502). Novo has asked that this motion be held in abeyance until the Court has resolved the jurisdictional motion and issues raised in the validity trial. The request is

DENIED; it is important that the Court have an understanding of the full range of issues to be decided in the case and the parties' positions.

SO ORDERED.

S/Avern Cohn
AVERN COHN
UNITED STATES DISTRICT JUDGE

Dated: September 16, 2010

I hereby certify that a copy of the foregoing document was mailed to the attorneys of record on this date, September 16, 2010, by electronic and/or ordinary mail.

S/Shawntel Jackson
Relief Case Manager, (313) 234-5160